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DIABETES

Status of the Disease Among American Indians, Blacks, and Hispanics

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Mr. Chairman and Members of the Committee:

It is a pleasure to be here today to share with you the preliminary results of our ongoing work on diabetes in minority populations living in the United States. In our testimony today, we present information on (1) the epidemiology of diabetes among American Indians, blacks, and Hispanics; and (2) existing federal funding for research on diabetes, especially that targeted to American Indian, black, and Hispanic population groups.

BACKGROUND

Before turning to the results of our work, let me say a few words about its context. The medical advances that have succeeded in eradicating the fatal infectious diseases of our earlier years have, as yet, left relatively untouched the major chronic diseases of later life. As more and more people live on into old age, chronic diseases--among them diabetes--are emerging as major causes of death and disability.

Diabetes refers to a number of conditions or syndromes characterized by the body's inability to produce or respond to insulin. There are two major types of diabetes: (1) insulin-dependent diabetes mellitus (IDDM), or type I, and (2) noninsulin-dependent diabetes mellitus (NIDDM), or type II. Still a third variation of the disease--not included in our analysis and therefore not discussed in this testimony--is gestational diabetes, an impaired glucose tolerance that is first detected during pregnancy. NIDDM accounts for 90-95 percent of all cases of diabetes mellitus. And at your request, we limited our analysis to this form of the disease. In our testimony, when we use the term "diabetes," we are referring primarily to NIDDM.

Diabetes is believed to affect 12-14 million Americans, half of whom are unaware that they have it. It is the seventh leading cause of death by disease, yet its etiology is still unknown. Estimates of its economic cost range from $14 billion to $20 billion annually (based upon diagnosed cases of diabetes), of which a significant portion is borne by the federal government in the form of direct medical costs and loss of revenue.

Diabetes can be detected by measuring the amount of sugar in the blood or urine. The condition is usually detected by an oral glucose tolerance test. Diabetes therapy is geared toward controlling high blood-glucose levels (hyperglycemia) and preventing diabetes complications. Once detected, diabetes can be controlled through an appropriate regimen that may include insulin injection, intake of oral drugs to lower blood glucose, diet therapy, a weight reduction program for persons who are overweight, and a program of exercise. Monitoring of blood glucose--by both the person with diabetes and by the physician-

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is an important adjunct to the care of diabetes. At this time, there is no cure for the disease.

Serious medical problems can occur if the condition is not controlled. A diabetic can lose consciousness or lapse into a coma due to high blood sugar levels over a period of time. The disease can also have long-term effects on most major organ systems. Diabetes is the leading cause of new blindness in adults, is implicated in one third of the cases of end-stage renal disease, accounts for 40 to 45 percent of nontraumatic amputations, and is associated with an increased risk of stroke and heart disease.

Federal Management

Federal diabetes-related activities are carried out by the National Institutes of Health (NIH) and other federal agencies, such as the Centers for Disease Control and the Indian Health Service. The National Institute of Diabetes and Digestive and Kidney Diseases (NIDDK), within NIH, is the major federal agency responsible for basic and clinical research on diabetes. Therefore, we have focused our review primarily on diabetes-related activities conducted by NIDDK.

WHAT DO WE KNOW ABOUT THE EPIDEMIOLOGY OF DIABETES IN AMERICAN INDIANS, BLACKS, AND HISPANICS?

Concerned about the fact that minorities have a higher rate of uninsurance and a higher rate of diabetes than whites, this Committee asked GAO to present the epidemiology of diabetes among American Indians, blacks, and Hispanics. Epidemiology is the study of the distribution of diseases in defined populations and of the factors affecting this distribution. The objectives of epidemiologic investigations are to (1) determine the extent of disease problems in the community, (2) investigate the cause or causes of the disease, (3) study the natural history of the disease, (4) develop a basis for prevention programs, and (5) evaluate the effectiveness of preventive and therapeutic programs.

To present this information to you, we reviewed literature on the prevalence and incidence of diabetes, including risk factors associated with the disease. In addition, we examined three federal sources of data on diabetes: (1) the National Health and Nutrition Examination Survey 1976-80 (NHANES II), (2) the Hispanic Health and Nutrition Examination Survey 1982-84 (HHANES)--both conducted by the National Center for Health Statistics--and (3) the health care data base of the Indian Health Service (IHS), which is a compilation of the medical records of all patients seen in any of the 432 IHS facilities.

These facilities provided care for approximately 86 percent of the 1987 estimated IHS service population of 1,016,815.[1]

Prevalence

Diabetes prevalence refers to both the proportion of people affected by diabetes and the frequency distribution of different levels of one or more attributes (for example, weight or arterial pressure) within a defined population at a particular point in time. It indicates the magnitude of the disease in the population. The prevalence rate can be based on previously diagnosed cases of diabetes and/or cases that had been undiagnosed but were detected through a screening program.

We found that American Indians, blacks, and Hispanics are disproportionately affected by the disease. Pima Indians have the highest prevalence of diabetes, followed by Puerto Ricans, Mexican Americans, blacks, Cubans, and all American Indians. Whites have the lowest prevalence of diabetes.

The age-standardized prevalence rates of diabetes are shown in table 1. Pima Indians had seven times the prevalence rate of whites; among Mexican Americans and Puerto Ricans, the rates were twice that of whites. The prevalence rates among all American Indians, Cubans, and blacks were 50 to 60 percent higher than the rate in whites.

Incidence

The rate of diabetes incidence measures the probability or risk that a healthy person will develop the disease during a specified period of time. It permits one to determine whether the probability of developing the disease differs in different populations or time periods, and whether it also differs in relationship to suspected causal factors.

There is a paucity of incidence data on diabetes among minority populations, with few exceptions. Incidence studies require follow-up of the same individuals over time. They are more difficult and costly than studies of prevalence. The limited data that do exist suggest that incidence rates of diabetes are higher in minority populations than in whites.

The only data that we were able to identify on Hispanics was for Mexican Americans who participated in the San Antonio Heart Study. This study followed Mexican American and white individuals living in San Antonio, Texas. Overall, the incidence

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[1]IHS provides services for approximately 56 percent of the American Indian population.

Table 1: Age-Standardized Prevalence Rates of Diabetes Among
          Whites, American Indians, Blacks, Hispanics, and Pima
          Indians 20-74 years of age, in the U.S. Population[a]

Population group	Rate	Rate relative to whites
White	6.2%	1.0
American Indian[b]	9.1	1.5
Cuban	9.3	1.5
Black	10.2	1.6
Mexican American	13.0	2.1
Puerto Rican	13.4	2.2
Pima Indian[c]	43.4	7.0

[a]Rates for whites, Cubans, blacks, Mexican Americans, and Puerto
Ricans are based on previously diagnosed and undiagnosed cases of
diabetes. Undiagnosed cases were detected by administering an
oral glucose test to a subsample of the study population. Rates
for American Indians and Pima Indians are based on previously
diagnosed cases of diabetes. It is likely that there are fewer
undiagnosed cases of diabetes in American Indians than other
racial groups because of the numerous community education
programs and free health care services that are available to
American Indians. Thus, it is reasonable to compare the rates,
although it is likely that the total prevalence of diabetes in
American Indians and Pima Indians is higher than indicated in the
table.

[b]The rate for American Indians is based on persons 15 years of
age and older, 1990 (age-adjusted to the 1980 U.S. population).
It is likely that the prevalence rate for American Indians 20 to
74 years of age would be higher than the rate for persons 15
years of age and older because increasing age is a risk factor
for diabetes.

[c]The rate for Pima Indians is based on persons 25-64 years of
age, 1981-88. The rates are not age-adjusted. The Pima Indians,
who have the highest recorded prevalence rate of diabetes in the
world, have been studied for over 25 years.

Source: Hispanic Health and Nutrition Examination Survey 1982-84
(HHANES); National Health and Nutrition Examination Survey 1976-
80 (NHANES II); Indian Health Service, 1991; W.C. Knowler, et
al., "Diabetes Mellitus in the Pima Indians: Incidence, Risk
Factors and Pathogenesis," Diabetes/Metabolism Reviews, 6:1
(1990), 1-27.

rate of diabetes in Mexican Americans was found to be over 3 times greater than that for whites, but it varied from slightly under 3 times as great for adults aged 45 to 64 years to as much as 5.5 times as great for adults aged 35 to 44 years. (See table 2.)

Age- and sex-specific incidence rates of diabetes in Pima Indians are shown in figure 1. Averaged over the 10-year periods, the incidence rate increased by about 50 percent in most age and sex groups. It has been reported that the age- and sex-specific incidence rate among Pima Indians was 19 times higher than that for a predominantly white population in Rochester, Minnesota.[2]

We were not able to locate any incidence data on other subgroups of American Indians and Hispanics or on blacks. Although incidence rates can be calculated from prevalence data where data are available on the duration of the disease, the lack of such information with regard to minority populations prevented us from making this calculation. In the absence of information on either the incidence or the duration of the disease in minority populations, it is impossible to say whether the natural history of the disease is the same or different in the various minority populations.

Risk Factors

The literature on diabetes suggests that several factors can be used to predict the occurrence of the disease. These include age, sex, metabolic factors, genetics, level of physical activity, and lifestyle.

In all population groups, the prevalence of diabetes increases with increasing age, and females have higher rates than males.

Across most population groups, there is an association between an impaired glucose tolerance (IGT) and the development of diabetes. The progression of IGT to diabetes is associated with level of obesity, a family history of diabetes, and high insulin levels (hyperinsulinemia). Hyperinsulinemia in itself is a risk factor, and its consistency as an indicator across population groups suggests that the nature and pathogenesis of diabetes are similar across populations.

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[2]W.C. Knowler, P.H. Bennett, R.F. Hamman, et al., "Diabetes Incidence and Prevalence in the Pima Indians: A 19-Fold Greater Increase than in Rochester, Minnesota," American Journal of Epidemiology, 108 (1978), 497-505.
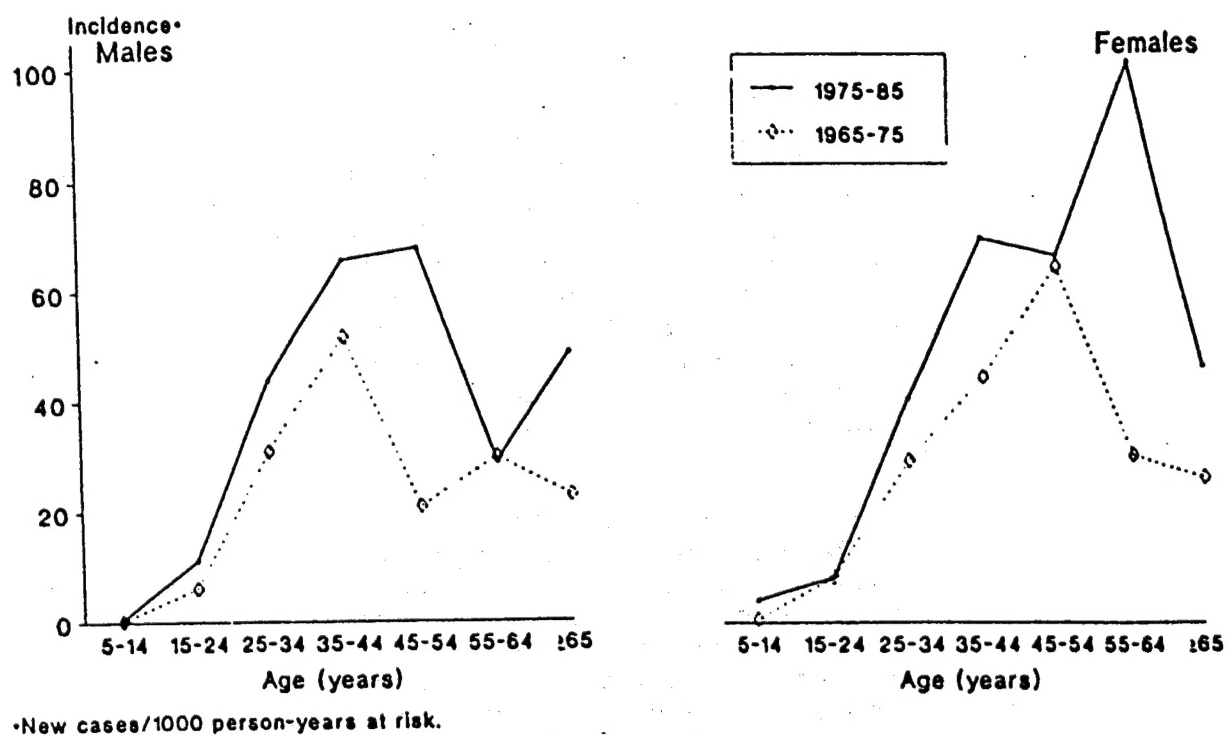
Table 2: Eight-Year Incidence of Diabetes in Mexican Americans
and Whites[a]

Age (yr)	Mexican Americans	Whites	Relative risk
25-34	7/171 = 4.1%	0/67 = 0.0%	--
35-44	11/184 = 6.0	1/89 = 1.1	5.5
45-54	11/152 = 7.2	2/76 = 2.6	2.8
55-64	10/90 =11.1	3/73 = 4.1	2.7
TOTAL	39/597 = 6.5	6/305 = 2.0	3.3

[a]The incidence rate was based on the 8-year period between
1979-82 and 1987-90.

Source: M.P. Stern and S.M. Haffner, "Type II Diabetes and Its
Complications in Mexican Americans," Diabetes/Metabolism Reviews,
6:1 (1990), 29-45.

Figure 1. Age- and Sex-Specific Incidence Rates of Diabetes in
         Pima Indians, 1965-75 and 1975-85

Source: W.C. Knowler, et al., "Diabetes Mellitus in the Pima
Indians: Incidence, Risk Factors and Pathogenesis,"
Diabetes/Metabolism Reviews, 6:1 (1990) 1-27.

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Across all population groups, an association between diabetes and specific genetic markers has been found. However, the role of these genetic markers in the development of diabetes is unclear. It is important to note that a genetic susceptibility to diabetes is a necessary but not sufficient condition for the development of the disease. It appears that certain environmental and lifestyle factors are necessary to trigger the disease in susceptible persons.

It has been found that the degree of Native American heritage in an individual is associated with an increased risk of developing the disease.[3] In one Native American community, the prevalence of diabetes among members of full Native American heritage was approximately double that of the non-Native American members. Those members of half Native American heritage had an intermediate prevalence rate. Although it has been hypothesized that the high prevalence of diabetes in Mexican Americans is partly a function of their admixture of Native American heritage, Puerto Ricans--who have equally as high a rate of diabetes as Mexican Americans--have a much lower degree of Native American heritage than Mexican Americans.

An extremely strong association has been found between a family history of diabetes and the development of the disease. For instance, the risk for an individual whose identical twin has been diagnosed with diabetes is nearly 100 percent. Siblings of persons with diabetes who are not identical twins have up to six times as great a risk of developing diabetes as siblings of age-matched persons without diabetes. The risk is doubled in children whose parents have developed diabetes. Studies that compare rates of disease between twins must be interpreted with caution as twins may experience very similar environments, thus making it difficult to explain the separate effects of heredity and environment on development.

The literature suggests that physical inactivity contributes to the development of diabetes. Physical inactivity has been associated with the development of abnormal glucose tolerance and higher insulin levels. Conversely, exercise can improve glucose tolerance and reduce insulin secretion, thereby reducing the risk of the disease. Physical inactivity also aids the development of obesity, which is another major risk factor for diabetes. Our understanding of the relationship between obesity and diabetes is largely based upon research with the Pima Indians, where the findings suggest that obesity is more strongly associated with the development of diabetes in younger adults than in older.

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[3]W.C. Knowler, R.C. Williams, et al., "Gm^{3,5,13,14} and Type 2 Diabetes Mellitus: An Association in American Indians with Genetic Admixture," American Journal of Human Genetics, 43 (1988), 520-526.

However, the mechanism by which obesity encourages the development of diabetes is unknown at this time.

While diet has long been thought to be a factor in the development of diabetes, there is no empirical evidence to suggest that diet is directly related to the genesis of the disease. Nonetheless, it has been found that migrant populations, who had higher rates of prevalence of diabetes than the same populations in their countries of origin, had diets that were higher in caloric content and contained more refined carbohydrates.[4] However, these migrant populations were also more sedentary and had higher rates of obesity than their counterparts in the country of origin.

HOW MUCH OF THE FEDERAL FUNDING FOR RESEARCH ON DIABETES IS TARGETED TO AMERICAN INDIANS, BLACKS, AND HISPANICS?

You also asked us to present information on the amount of federal funding for research on diabetes that is targeted to American Indian, black, and Hispanic population groups.

As we have mentioned, the National Institute of Diabetes and Digestive and Kidney Diseases (NIDDK) is the major federal agency responsible for basic and clinical research on diabetes. In order to answer your question, we asked NIDDK for information on (1) the total number of intramural and extramural NIDDM and related research projects and (2) the total amount of the funds provided for this research. In addition, we asked NIDDK to categorize this information by type of research and the ethnic composition of the study population. The officials of NIDDK told us that the existing NIH data bases (CRISP and IMPACT) do not include information on the number of minority participants in human research, nor do they categorize types of human research. However, NIDDK officials used their personal knowledge of the research to provide the data requested. With this source in mind, we consider the data presented in our findings as estimates rather than as the actual number of projects and amounts of funding that NIDDK targets to diabetes research involving American Indians, blacks, and Hispanics.

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[4]Kawate, R., Yamakido, M., Nishimoto, Y., et al.: "Diabetes Mellitus and Its Vascular Complications in Japanese Migrants on the Island of Hawaii," Diabetes Care 2 (1979), 161-170.

<u>FINDINGS</u>

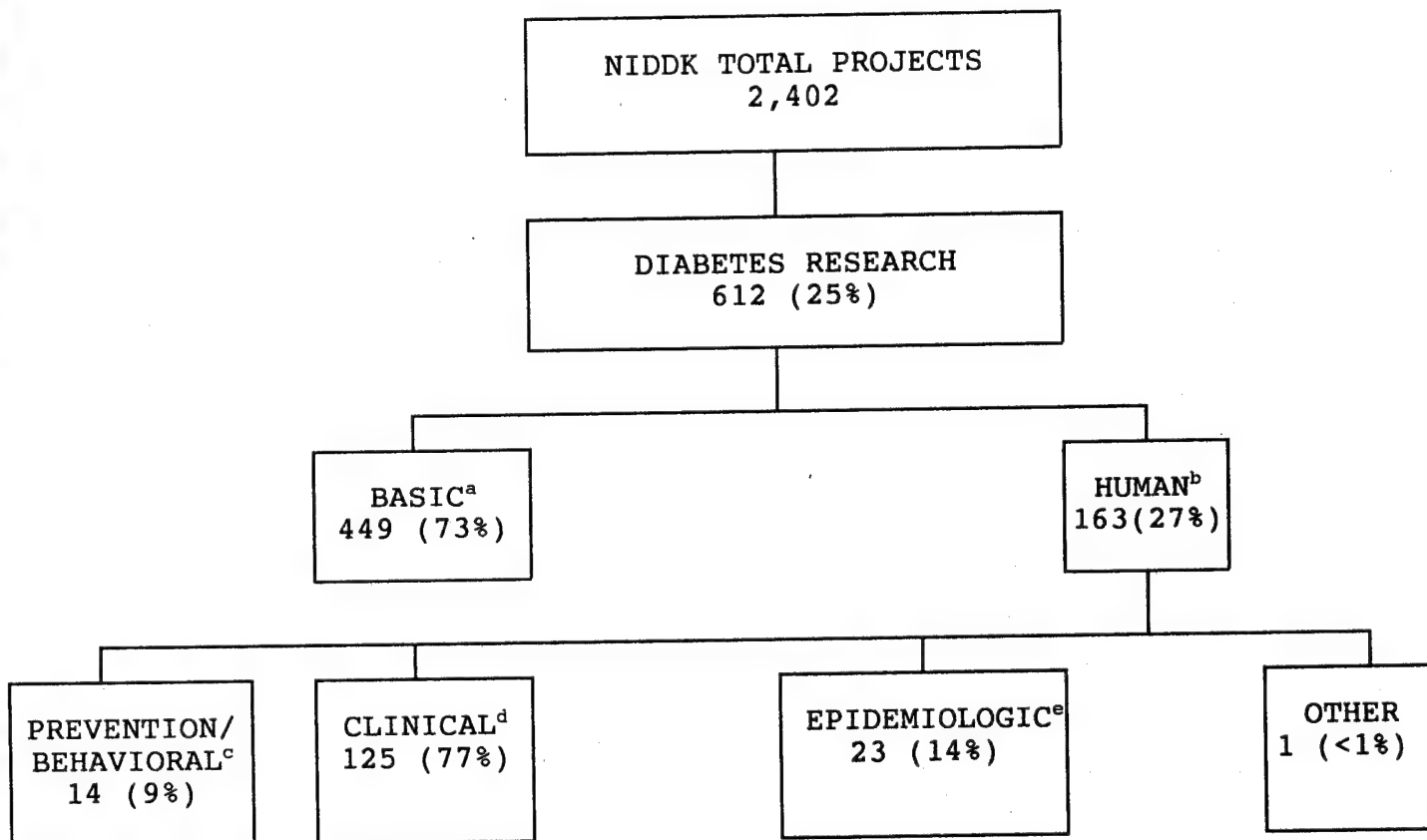Our findings on the amount of resources devoted to diabetes research are as follows[5]:

o In fiscal year 1991, NIDDK funded 612 diabetes research projects totaling $130 million (see figures 2 and 3), which represented 25 percent of all NIDDK projects and 21 percent of the NIDDK budget;

o almost three fourths of both the total number of projects and the funds budgeted for diabetes research were devoted to basic research, with the remainder devoted to human research (see figures 2 and 3);

o of the total number of projects devoted to diabetes human research (163), three fourths were devoted to clinical research, with the remainder involving epidemiological, prevention/behavioral, and other research (see figure 2);

o of the total funds devoted to diabetes human research ($36 million), two thirds were devoted to clinical research, with the remainder going to epidemiological, prevention/behavioral, and other research (see figure 3).

Our findings on the amount of diabetes research targeted to American Indian, black, and Hispanic population groups are as follows:

o Fifty-three percent of the $36 million devoted to diabetes human research (that is, $19.2 million) was targeted to American Indian, black, and Hispanic population groups (see table 3);

o Fifty-two percent of the 163 projects (that is, 84 projects) devoted to diabetes human research were targeted to American Indian, black, and Hispanic population groups (see table 3);

o Sixty-three percent of the $4.4 million devoted to prevention/behavioral research, 41 percent of the $24.4 million devoted to clinical research, and 91 percent of the $7.2 million devoted to epidemiological research went to

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[5]Although we received data from NIDDK on fiscal years 1990-91, we present findings only on fiscal year 1991. The trends were similar across both fiscal years.

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Figure 2: Number and Percent of NIDDK Projects Devoted to
Diabetes by Type of Research

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                    │  NIDDK TOTAL PROJECTS    │
                    │         2,402            │
                    └──────────────────────────┘
                                 │
                    ┌──────────────────────────┐
                    │   DIABETES RESEARCH      │
                    │      612 (25%)           │
                    └──────────────────────────┘
                                 │
              ┌──────────────────┴──────────────────┐
         ┌─────────────┐                    ┌─────────────┐
         │  BASICᵃ     │                    │  HUMANᵇ     │
         │  449 (73%)  │                    │ 163(27%)    │
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│ PREVENTION/  ││  CLINICALᵈ   │  │  EPIDEMIOLOGICᵉ     │ │   OTHER      │
│ BEHAVIORALᶜ  ││  125 (77%)   │  │  23 (14%)           │ │  1 (<1%)     │
│  14 (9%)     ││              │  │                     │ │              │
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[a]Includes basic nonhuman research and molecular and cellular
research using established human cell lines.
[b]Includes projects identified as receiving NIH Institutional
Review Board Approval for the use of human subjects; for example,
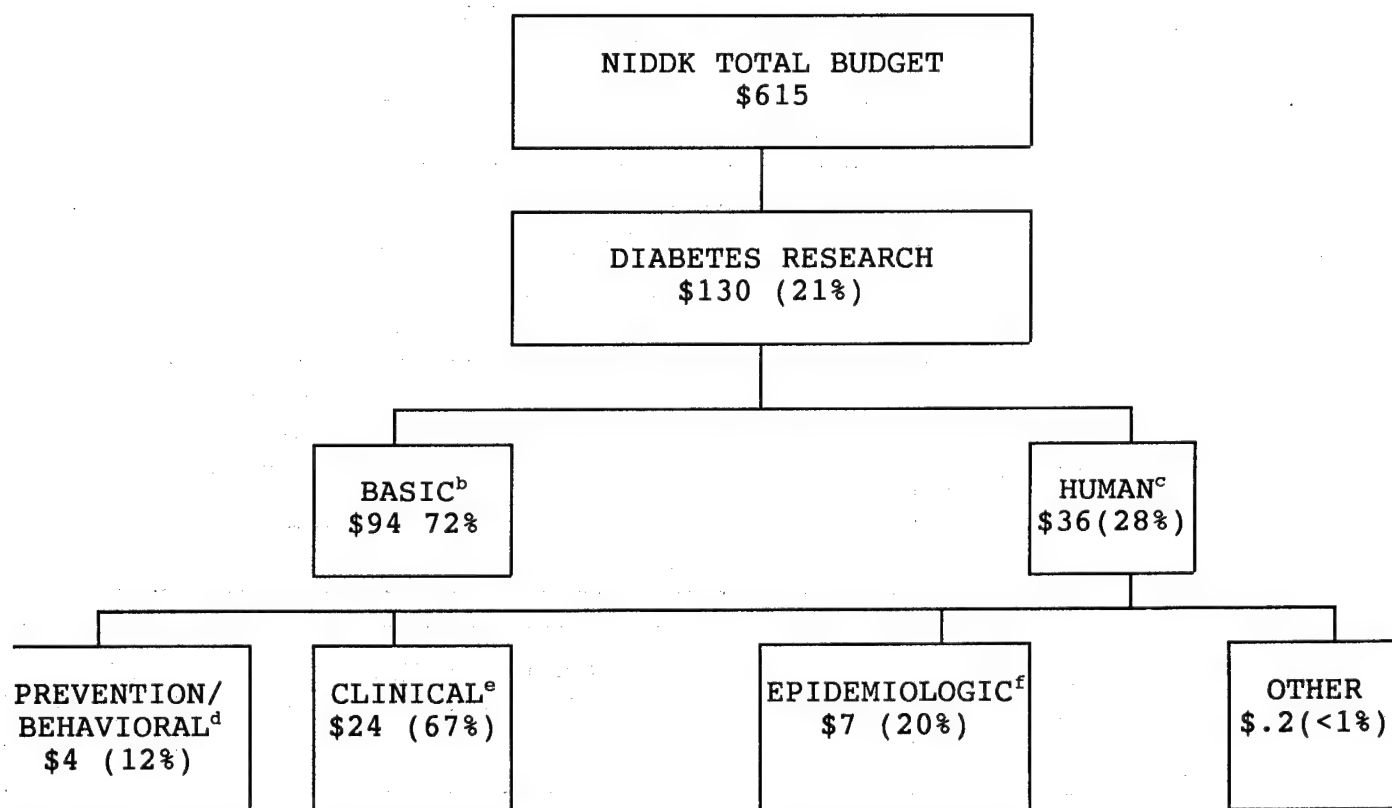research involving the use of patients or patient-derived
material.
[c]Projects such as those dealing with patient compliance or the
manner in which physicians educate the diabetic patient.
[d]Projects involve human subjects or tissue and are oriented
towards improvement of human therapies.
[e]Population-based studies of the prevalence of the disease.

Source: National Institute of Diabetes and Digestive and Kidney
Diseases, 1991.

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Figure 3: Amount and Percent of NIDDK Funds Devoted to Diabetes by Type of Research[a]

[a]Dollar amounts in millions.
[b]Includes basic nonhuman research and molecular and cellular research using established human cell lines.
[c]Includes projects identified as receiving NIH Institutional Review Board Approval for the use of human subjects; for example, research involving the use of patients or patient-derived material.
[d]Projects such as those dealing with patient compliance or the manner in which physicians educate the diabetic patient.
[e]Projects involve human subjects or tissue and are oriented towards improvement of human therapies.
[f]Population-based studies of the prevalence of the disease.

Source: National Institute of Diabetes and Digestive and Kidney Diseases, 1991.

Table 3: Number and Percent of Projects and Funding for Diabetes Research by Type of Research and Study Population[a]

Type of research	Population group	Projects #	Projects %	Funding[b] $	Funding[b] %
Human (Total)	American Indian	46	28	7,458	21
	Black	15	9	4,145	11
	Hispanic	4	2	1,671	5
	Multiracial[c]	19	12	5,965	17
	White	77	47	16,728	46
	TOTAL	163	100	36,089	100
o Prevention/ Behavioral	American Indian	5	36	358	8
	Black	5	36	2,048	47
	Hispanic	0	0	70[d]	2
	Multiracial[c]	1	7	285	7
	White	3	21	1,600	37
	TOTAL	14	100	4,361	100
o Clinical	American Indian	35	28	6,042	25
	Black	6	5	1,095	4
	Hispanic	1	<1	293	1
	Multiracial[c]	12	10	2,559	11
	White	69	55	14,246	58
	TOTAL	125	100	24,357	100
o Epidemiologic	American Indian	6	26	1,058	15
	Black	4	17	1,002	14
	Hispanic	3	13	1,308	18
	Multiracial[c]	6	26	3,121	44
	White	4	17	666	9
	TOTAL	23	100	7,155	100

[a]Totals for human and clinical research categories include two projects ($122,000) that were targeted to another population group; the human research for whites includes another type of project ($216,000).
[b]Dollar amounts in thousands.
[c]Involved only non-white populations.
[d]The amount from two multiracial projects that targeted Hispanics.
Source: NIDDK, 1991.

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projects that involved American Indian, black, and Hispanic population groups (see table 3).

Our findings on the amount of resources devoted to any one of the minority population groups for each type of diabetes human research were as follows:

o eight percent of the funding for prevention/behavioral research, 25 percent of the funding for clinical research, and 15 percent of the funding for epidemiological research were targeted to the American Indian population group (see table 3);

o forty-seven percent of the funding for prevention/behavioral research, 4 percent of the funding for clinical research, and 14 percent of the funding for epidemiological research were targeted to the black population group (see table 3);

o Two percent of the funding for prevention/behavioral research, one percent of the funding for clinical research, and 18 percent of the funding for epidemiological research were targeted to the Hispanic population group (see table 3).

Putting this together another way, 15 percent of the $130 million budget for diabetes research was devoted to prevention/behavioral, clinical, and epidemiological research that involved American Indian, black, and Hispanic population groups. Specifically, 2 percent was devoted to prevention/behavioral research, 5 percent for epidemiological research, and 8 percent for clinical research.

DISCUSSION

We found that although 53 percent of the $36 million devoted to diabetes human research went to minority-targeted projects, very few clinical research projects (the area of heaviest funding, at $24 million) and prevention/behavioral research projects were targeted to Hispanic and black population groups. For example, in 1991, only one clinical research project (funded at about $293,000) and no prevention/behavioral research project targeted the Hispanic population. Further, only 6 clinical research projects and 5 prevention/behavioral research projects targeted the black population.

Further, it is well understood that there are differences in the rates of diabetes among minority subgroups. However, to date, the vast majority of research targeting American Indians has been focused on the Pima Indians. The Pima population (approximately 8,000) is a small fraction of the nearly two

14

million Native Americans. In the same way, a large majority of the research targeting Hispanics has involved Mexican Americans, yet Puerto Ricans--who experience slightly higher rates of diabetes than Mexican Americans--were not the target of any of NIDDK's research projects.

We believe that additional information on the typology of diabetes research would assist in the development of a better understanding of diabetes in minorities and of the federal response to this health issue. Such an understanding would be based upon research projects whose objectives, design, and sample size allowed for the study of the effect of race on outcome measures. Once developed, this information could help determine federal research priority and funding levels.

NIDDK officials told us that it is inappropriate to evaluate the adequacy of the federal response to diabetes in minority populations by examining funds targeted to these populations. They stated that the vast majority of any research on diabetes is directly beneficial to minority diabetics because the cause and treatment of the disease are similar across all population groups. However, without an established etiology for the disease; without knowing its natural history in minority populations; and in the face of large disparities of prevalence and risk across both non-minority and minority groups (as well as across the various minority subgroups themselves), NIDDK's assertion concerning the race-neutrality of the disease seems to be more an empirical question than a substantiated fact.

At this time, it is difficult to determine from the NIH data base the actual amount of resources being targeted to minority diabetics. While NIDDK officials were able to calculate the amounts based on personal knowledge of the research, GAO believes that maintaining a systematic data base is essential in order to monitor both the representation of minority population groups in federal research on diabetes and the progress being made in understanding the disease itself.

Finally, NIDDK does not attempt to collect information on the race of the individuals from whom the human cells are derived in their basic research. It is crucial that NIDDK have this information on donor race for several important reasons. First, since the gene(s) for diabetes is likely to be more frequent in certain populations, knowing the race of the donor may save time and effort in understanding the role of genetics in the disease. Further, it is sensible to search for a diabetes gene in populations that experience a high incidence of the disease. The benefits of this approach could extend to all diabetics, regardless of race. Second, since race has been found to be an important risk factor for diabetes, this information can contribute to our understanding of not only the pathogenesis of

the disease but also the degree to which findings in one racial group in fact generalize to other populations.

SUMMARY

Based on our review of the literature, examination of extant data, and interviews with experts and officials of NIDDK, our findings on diabetes in minority populations are as follows:

First, the prevalence of diabetes is higher in American Indians, Hispanics, and blacks than in whites. Second, there is a paucity of research on the incidence of diabetes in minority populations. However, the limited data suggest higher incidence rates in minorities than whites. Third, it appears that certain environmental and lifestyle factors are necessary to trigger the disease in persons who are genetically susceptible to it. Fourth, we do not know whether the natural history of the disease is the same or different across different population groups. This shortcoming represents a significant gap in our understanding of the disease since this information is needed to help determine why the prevalence of diabetes and the incidence of complications from diabetes are higher in minorities than in whites.

Fifth, while slightly more than half the funds for diabetes human research as a whole are targeted to minorities, only a small percentage of the total diabetes funding and a small number of projects are targeted to Hispanic and black population groups in the specific areas of prevention/behavioral and clinical research. Further, some subgroups of American Indians and Hispanics are not represented at all. Sixth, the NIH data base cannot be used to determine the actual amount of resources that are being targeted to diabetes in minorities. Finally, NIDDK does not make an attempt to collect information on the race of the individuals from whom the human cells are derived in their basic research.

Mr. Chairman, this concludes my remarks. I would be happy to answer any questions you may have.